

REMARKS/ARGUMENTS

Claims 6-25 are pending. In Claim 6, the material introduced into the gene expression vector has now been identified as a “polynucleotide” instead of a gene. Other minor changes have been made to the claims to improve their clarity. Accordingly, the Applicants do not believe that any new matter has been introduced.

The Applicants thank Examiner Helmer for the courteous and helpful discussion of November 21, 2005. It was indicated that the term “gene” may be retained to refer to conventional elements, such as the *ipt* gene, but that the inserted material should be identified as a “polynucleotide” to avoid confusion as to whether the word gene referred just to the coding sequence or coding a regulatory sequences. The explants described on page 200 of Budar et al., Plant Science 46:195 were discussed. The claim language has now been clarified in view of this discussion.

Rejection - 35 U.S.C. §112, second paragraph

Claims 6-25 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. For clarity, the material inserted into the gene introduction vector has been identified as a polynucleotide instead of a gene. However, conventional terminology for elements such as marker genes and the *ipt* gene are retained, also for clarity. Since these elements are conventional and are Applicants respectfully submit that the following terms would not be indefinite to one of skill in the art in light of the specification.

The term “gene” refers to a segment of DNA that is involved in producing a polypeptide chain, which may optionally include regions preceding and following the coding DNA as well as introns between the exons.

The term “auxin precursor and/or analogue” is described in the specification on page 6, lines 3-7. An auxin precursor is a substance that is converted into an auxin or into a

substance having physiological activity similar to that of an auxin, e.g., the auxin precursor indoleacetamide is converted to the auxin indoleacetic acid (IAA). Similarly an analogue of an auxin precursor is a substance that may be converted into an auxin analogue or a substance with auxin-like activity, e.g., the auxin analogue precursor naphthaleneacetamine (NAM) may be converted to the synthetic auxin analogue NAA.

Rejection - 35 U.S.C. §102

Claims 6-12, 16, 17 and 20 were rejected under 35 U.S.C. §102(a) as being anticipated by Budar et al., Plant Science 46:195. Budar does not anticipate the present invention because it does not disclose a selection method based on the expression of gene synthesizing an auxin or auxin analog as a selectable marker. The claimed method permits careful control of auxin synthesis by regulation of the concentration of auxin precursor in the selection medium (specification, page 7, last paragraph). On the other hand, Budar uses an antibiotic resistance gene, Km^R , as the selectable marker and do not recognize the benefits of a selection based on selective expression of an auxin gene. Moreover, there is no selection of redifferentiated tissue step in Budar.

<u>Claim 1</u>	<u>Budar et al.</u>
(A) transforming a plant cell with a gene introduction vector which comprises a desired polynucleotide sequence and a selectable marker gene which encodes an enzyme that synthesizes auxin from an auxin precursor or synthesizes an auxin analogue from an auxin analogue precursor,	Plant cell transformed with combination of Gene 2 + Km^R (see Fig. 3) Gene 2 is involved in the production of the auxins IAA and NAA (page 195, col. 2). Km^R is a selectable marker gene, but not a marker which synthesizes auxins.
(B) culturing the transformed plant cell in a medium containing the auxin precursor and/or analogue thereof under conditions suitable for producing a redifferentiated plant tissue from said transformed plant cell,	"Kanamycin resistant colonies were selected either in liquid of on solid medium" (page 199, col. 1).
(C) detecting and selecting the	"Kanamycin resistant plants were considered

redifferentiated plant tissue and	transformed" (page 202, first full paragraph). No "clearly abnormal phenotypes" were observed in transformant morphology (page 202, full first paragraph)
(D) culturing the redifferentiated plant tissue into a transgenic plant.	Kanamycin resistant colonies were transferred on the medium used for solid selection where they developed shoots. (page 199, col. 2).

Unlike the present invention in Budar et al. the selectable marker gene is a kanamycin resistance gene, not a gene that synthesizes auxin from a precursor. Budar also selects transformants based on kanamycin resistance and not on the basis of redifferentiated plant tissue. In fact, Budar indicates that transformants had no clearly abnormal phenotypes, precluding a phenotype-based selection. Kanamycin resistance is the indicia of transformation in Budar, but the ability to redifferentiate plant tissue is used in the claimed method. Budar cultivates kanamycin-resistant cells into plants, whereas the claimed method cultivates redifferentiated plant tissue into plants. Since Budar does not disclose all the elements and steps of the claimed method, this rejection should be withdrawn.

Rejection - 35 U.S.C. §103

Claims 6-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Budar et al., Plant Science 46:195, in view of Endo et al., Plant Cell Reports 20:923-928 and Ebinuma et al., U.S. Patent No. 5,965,791.

Budar has been addressed above and does not disclose or suggest a method involving expression of an auxin synthesis gene and a phenotype-based selection of redifferentiated plant tissue.

Endo et al. also do not suggest or provide a reasonable expectation of success for the claimed method because in Endo the transformed cells contain both the *iaaH* and *iaaM* genes and produce auxin independently of the culture medium. There is no suggestion in Endo for

the selection method of the present invention which permits control of the amount of auxin produced by the transformed cells.

Control of auxin production is important for improving the selection efficiency, for example, by reducing “escape” phenomena where a transformed cell produces auxin which diffuses to nearby untransformed (non-gene introduced) cells and causes them to express the same phenotype as transformed cells, see the specification, page 2, last paragraph. The Examples and Comparative Examples in the specification show the improved selection efficiency provided by using a method where an auxin precursor is present in the selection medium. For example, as shown in Tables 1 and 2 on pages 17 and 19 of the specification, a significantly higher selection frequency was obtained by culturing transformants in the presence of 1 or 10 μ M of the auxin analogue precursor NAM (38.1% and 50.0%) as compared to transformants selected in a medium containing corresponding concentrations of the auxin analogue NAA (22.2% and 7.7%).

Ebinuma et al. is cited as teaching particular selectable markers (*ipt* gene, GUS gene, hygromycin resistance gene, etc.) and woody plants like *Eucalyptus* and *Populus*, but does not disclose or suggest a selection method based on the expression of an auxin synthesis gene and selection of plant tissue that is redifferentiated after the expression of such a gene.

Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection - 35 U.S.C. §103

Claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over Endo et al., Plant Cell Reports 20:923-928. The Official Action suggests that it would have been obvious to omit the *iaaM* gene of Endo since it may be desirable to use fewer genes to obtain a less complex vector. However, there is no suggestion in Endo that omission of the *iaaM* gene would provide any benefit at all. That is, the cited prior art provides no motivation for

deleting this gene. Further more, there is no secondary reference indicating that *iaaM* should not be included in the Endo vector or that a vector without *iaaM* would exhibit the superior properties discovered by the present inventors. Moreover, the secondary considerations of non-obviousness, including the demonstration of an unexpected or superior activity for a product, are applicable in the analysis of both product and method claims. Therefore, the Applicants reiterate their prior argument below and request that this rejection be withdrawn.

With respect to Claim 25 (vector), unlike the vector of Endo, the vector constructs of the present invention (which do not include all the genes in the auxin production pathway) result in better control over the redifferentiation of transformed plant cells when used in conjunction with a medium containing an auxin precursor, see page 11 of the specification. The Endo vector comprises both the *iaaM/H* genes in combination with an *ipt* gene. Endo does not supply any motivation for removing the *iaaM* gene from the vector and teaches away from this. Endo, page 923, first column, indicates that the combination of the *ipt* gene and the *iaaM/H* genes can result in the production of both auxin and cytokinin. However, deletion of the *iaaM* gene would prevent the conversion of tryptophan to indoleacetamide and thus be ineffective for producing the auxin required by the Endo method. Since there is no suggestion to add an auxin precursor to the medium in Endo, this reference teaches away from deleting the *iaaM* gene because in the absence of the auxin precursor, the use of a vector without the *iaaM* gene would be ineffective for supplying auxin and cytokinin required by the Endo method. Moreover, there is no reasonable expectation of achieving the benefits of modulating the cytokinin/auxin ratio in the plant hormone gene introduced cell by using such a vector in Endo.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.


Respectfully submitted,

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